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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,229	06/25/2001	Richard Ian Christopherson	650061.401USPC	2287
500 7590 11/28/2007 SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVE SUITE 5400 SEATTLE, WA 98104			EXAMINER SMITH, CAROLYN L	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 11/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/869,229	CHRISTOPHERSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 58,71 and 73-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58,71 and 73-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>02082007, 06062007, 08212007</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission, filed 8/31/07, has been entered.

Amended claims 58, 71, and new claims 75-76, filed 8/31/07, are acknowledged.

Claims herein under examination are 58, 71, and 73-76.

### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title recites an assay to detect a binding partner whereas the instant claims are directed to an assay device for identifying a leukemia of T-cell, B-cell, or myeloid lineage in a subject.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58, 71, and 73-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 58 recites the limitation "the immunoglobulins" and "the immunoglobulin" in lines 10 and 11. There is insufficient antecedent basis for these limitations in the claim. While there is previous mention of "immunoglobulin molecules" and "immunoglobulin molecule", there is not previous mention of "immunoglobulins" and an "immunoglobulin". Correction is suggested by amending the rejected terms to recite "the immunoglobulin molecules" and "the immunoglobulin molecule". Claims 71 and 73-76 are also rejected due to their dependency from claim 58.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 58, 73, and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang (Journal of Immunological Methods, Volume 65, 1983, pages 217-223).

Chang discloses an antibody matrix method using an solid surface and an array of antibodies to determine the proportion of specific subsets of T-cell, B-cell, or monocytes in a mononuclear cell fraction (abstract and page 223, first paragraph) and determining a specific allotype of a surface antigen on the cells of an individual and analyzing functionally different cell subpopulations that express distinct differentiation antigens (page 222, last paragraph), and using human peripheral blood mononuclear cells (page 218, third paragraph and page 219, second paragraph) which represents an assay device for identifying a leukemia of T-cell, B-cell

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or myeloid lineage in a subject, said device comprising a solid support and an array of immunoglobulin molecules, as stated in instant claim 58. In Figure 1, Chang discloses mononuclear cells binding to a 10 X 10 antibody matrix (Figure 1 caption), antibodies of distinct specificities are coated on small areas forming matrix-like arrays on glass coverslips wherein the antibody spots on an area can be coated with 25, 100, or 400 spots, as well as multiple determinations of specific cell surface antigens wherein the antibody spots serve as minute specific immunoadsorbents for cells bearing the surface antigens (abstract) which represents an array that comprises 7 to about 1000 discrete regions on the solid support and each discrete region comprising an immunoglobulin that is specific for a single distinct cell surface marker antigen on a leukocyte, as stated in instant claim 58. Chang discloses an array comprising 2 different antibodies (anti-Lyt 2.1 spots which are mIgG2A and anti-Lyt 2.2 spots which are mIgM) (page 221, last paragraph and page 218, first paragraph) as well as mIgG1 and HLA-DR (page 218, first paragraph and page 221, second paragraph) which represent an array comprising different immunoglobulin molecules wherein the cell surface marker antigens are selected from Table 4. Chang discloses arranging the anti-Lyt 2.1 and 2.2 spots alternately and the specific patterns of expression between them after applying cell samples (page 221, last paragraph to page 222, first paragraph; Figure 2A and 2B and their caption) and determining the proportion of specific subsets of T-cell, B-cell, or monocytes in a mononuclear cell fraction (abstract and page 223, first paragraph) which represents immunoglobulin molecules arranged such that specific binding of each discrete region to its respective distinct cell surface marker antigen on a leukocyte provides a pattern of expression that distinguishes leukemia of T-cell, B-cell, or myeloid lineage, as stated in instant claim 58. Chang discloses using monoclonal antibodies

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(page 218, first line and first paragraph; page 222, second paragraph under Discussion section), as stated in instant claims 73 and 75. Chang discloses cells binding to surfaces coated with antibody molecules that react with antigens on the surface of the cells (page 217, last paragraph). Chang discloses if antibodies of relevant but distinct specificities can be prepared and purified, they can be coated on a small area of a surface and be used to analyze antigens (page 220, second paragraph). Chang discloses this antibody matrix immunoadherence method allows testing of all antibodies to be processed on one coated-glass surface at the same time (page 222, first paragraph under Discussion section).

Thus, Chang anticipates the limitations in instant claims 58, 73, and 75.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 58, 71, 73 and 75-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang (Journal of Immunological Methods, Volume 65, 1983, pages 217-223) in view of Brandt et al. (US 4,797,356).

Chang describes the limitations of instant claims 58, 73, and 75, as described in the 35 USC 102 rejection above. Chang does not describe covalent binding to the solid support (instant claim 71) or an array comprising antigen-binding fragments of the immunoglobulin molecules (instant claim 76).

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Brandt et al. describes immobilizing antibodies and antigen-binding fragments to a solid support by covalent binding (col. 2, lines 6-16 and col. 4, lines 12-20), as stated in instant claims 71 and 76.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the assay device of Chang by immobilizing antibodies and antigen-binding fragments to a solid support by covalent binding as taught by Brandt et al. wherein the motivation would have been to perform a conventional immunoassay protocol to indicate the presence of cancer, including leukemia (Brandt et al., col. 3, last paragraph to col. 4, second paragraph).

Thus, Chang in view of Brandt et al. make obvious instant claims 58, 71, 73 and 75-76.

Claims 58, 71, and 73-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang (Journal of Immunological Methods, Volume 65, 1983, pages 217-223) in view of Ceriani et al. (US 5,514,558).

Chang describes the limitations of instant claims 58, 73, and 75, as described in the 35 USC 102 rejection above. Chang does not describe covalent binding to the solid support (instant claim 71), using polyclonal antibodies (instant claim 74), or an array comprising antigen-binding fragments of the immunoglobulin molecules (instant claim 76).

Ceriani et al. describe covalently binding an antibody or fragment to a poly (amino acid)-coated solid support (claims 1 and 30; col. 8, lines 1-14; col. 15, lines 35-43) and using

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polyclonal antibodies and fragments (col. 17, line 57 to col. 18, line 10), as stated in instant claims 71, 74, and 76.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the assay device of Chang by including covalent binding of polyclonal antibodies and fragments as taught by Ceriani et al. wherein the motivation would have been to provide a higher sensitivity and specificity than other assays, as taught by Ceriani et al. (col. 1, lines 11-21).

Thus, Chang in view of Ceriani et al. make obvious the instant invention.

### *Conclusion*

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

November 2, 2007

/Carolyn Smith/  
Primary Examiner  
AU 1631